UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

STATE OF VERMONT and VERMONT AGENCY OF ADMINISTRATION Plaintiffs, v. MICHAEL O. LEAVITT, in his official capacity as Secretary of the United States Department of Health and Human Services and LESTER M. CRAWFORD, in his official capacity as Acting Commissioner of the United States Food and Drug Administration Defendants.	:	Case No. 2:04-CV-206

OPINION AND ORDER

I. Introduction

In Beebe Plains, Vermont, there is a street, appropriately named Canusa Avenue, that runs right along the United States-Canada border. Houses on the northern side of the street are in Canada while houses on the southern side are in Vermont. If a resident of the northern side of Canusa Avenue needs medication to control high cholesterol, he or she can purchase a 90-day supply of 20 milligram Lipitor for $170. On the southern side of the street, Vermont residents will have to dig much deeper if they need to purchase the same drug. The same 90-day supply of Lipitor costs about $330 in the United States.[1]

[1]Price estimates compiled from www.canadapharmacy.com and www.cvs.com, visited 25 May, 2005.

This price differential is far from unique. On average, brand-name drug prices are approximately 70% higher in the United States. Congressional Research Service Report for Congress, Importing Prescription Drugs: Objectives, Options, and Outlook 7-8 (Aug. 4, 2004). It has been estimated that United States consumers would have saved $59.7 billion if, during 2004, they had purchased all brand-name drugs at Canadian prices. Id. at 29. To put that figure in context, it is more than the gross national products of Kuwait, Iceland and Jamaica *combined*.[2]

Given the dramatic difference between United States and Canadian drug prices, it is unsurprising that many Americans are interested in buying prescription drugs in Canada. "Nearly five million shipments, comprising about 12 million prescription drug products with a value of approximately $700 million entered the U.S. from Canada alone in 2003." HHS Task Force on Drug Importation, Report on Prescription Drug Importation, ix (Dec. 2004) (hereafter "HHS Report"). As residents of a border state, most Vermonters can drive to Canada within two or three hours. Thus, Vermont residents are more likely to buy prescription drugs in Canada than most other Americans.

Vermont regulators have been concerned about high domestic drug prices and the increase in ad-hoc, personal importation of

[2]Gross domestic product estimates for 2004 are available at http://www.indexmundi.com/g/r.aspx?t=100&v=65 (visited May 25, 2005).

Canadian drugs by Vermont residents. In response to these concerns, plaintiff Vermont Agency of Administration ("VAA") submitted a citizen petition to the Food and Drug Administration ("FDA") requesting that the FDA allow the Vermont State Employee Medical Benefit Plan ("VTSEMBP") to "establish a program for the orderly individual importation of prescription medications." Citizen Pet. at 2 (Dec. 4, 2003) (Doc. 1, Ex. A). The FDA denied this petition. Letter from William K. Hubbard to Michael K. Smith of 8/4/05 (Doc. 1, Ex. B) (hereafter "FDA Decision").

Plaintiffs VAA and the State of Vermont (collectively "Vermont") filed this lawsuit on August 19, 2004, challenging the FDA's denial of the citizen petition. Vermont claims that the denial was arbitrary and capricious in violation of the Administrative Procedure Act ("APA"). Vermont also seeks a declaratory judgment that 21 U.S.C. § 384(l)(1) violates Article I, § 1 of the United States Constitution by improperly delegating legislative power to the Executive Branch.

On November 29, 2004, the Defendants filed a Motion to Dismiss (Doc. 5) pursuant to Federal Rule of Civil Procedure 12(b)(6). The Defendants argue that they were required to deny Vermont's citizen petition because it proposed a drug importation scheme that violated federal law. Thus, the issue before the Court is the *legality* rather than the merit of Vermont's proposal. For the reasons set forth below, the Court grants the

Defendants' Motion to Dismiss.

II. Standard of Review

A. Rule 12(b)(6)

When deciding a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), a court must "construe the complaint in the light most favorable to the plaintiff, accepting the complaint's allegations as true." Todd v. Exxon Corp., 275 F.3d 191, 197-98 (2d Cir. 2001). A district court may grant a motion to dismiss for failure to state a claim only if "'it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.'" Id. at 198 (quoting Conley v. Gibson, 355 U.S. 41, 45-46 (1957)). Therefore, "'[t]he issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims.'" Id. (quoting Scheuer v. Rhodes, 416 U.S. 232, 236 (1974)). In general, when deciding a motion to dismiss, a court will consider the facts alleged in the complaint and any documents attached as exhibits or incorporated by reference. Cosmas v. Hassett, 886 F.2d 8, 13 (2d Cir. 1989).

B. Administrative Procedure Act

Under the APA, the Court must set aside any agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Under this standard, the Court must "determine whether the agency

has considered the pertinent evidence, examined the relevant factors, and articulated a satisfactory explanation for its action including whether there is a 'rational connection between the facts found and the choice made.'" J. Andrew Lange, Inc. v. F.A.A., 208 F.3d 389, 391 (2d Cir. 2000) (quoting Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962)). The Court's "review of an agency decision is generally confined to the administrative record compiled by that agency when it made the decision." Vt. Pub. Interest Research Group v. United States Fish & Wildlife Serv., 247 F. Supp. 2d 495, 514 (D. Vt. 2002). "The scope of review under the arbitrary and capricious standard is narrow and a court is not to substitute its judgment for that of the agency." Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983).

When the agency action is based on an interpretation of its governing statute, the Court must consider whether that interpretation is entitled to deference and, if so, how much. See United States v. Mead Corp., 533 U.S. 218 (2001). If a statute speaks clearly "to the precise question at issue," the Court "must give effect to the unambiguously expressed intent of Congress." Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842-43 (1984).

III. Factual Background

The following facts are taken as true for the purposes of

this motion. Vermont filed its citizen petition with the FDA on December 4, 2003. Compl. ¶ 17 (Doc. 1). Vermont explained that it wanted "authority to contract with providers to create a system under which its members have the option of forwarding a prescription to a Canadian firm where the prescription would be reviewed by a physician familiar with the member's medical history and re-written as a Canadian prescription, which would be forwarded to a licensed Canadian pharmacy to be filled and sent by mail to the member in the United States." Citizen Pet. at 2. Accordingly, Vermont requested the FDA to "issue regulations or otherwise commit to exercise its enforcement discretion to allow the VTSEMBP to establish a program for the orderly individual importation of prescription medications in a manner that promotes the safety and health of its members." Id. at 1-2. In the alternative, the petition requested that the FDA "issue guidance that such a program would be lawful under the statutes and regulations enforced by the Commissioner of Food and Drugs." Id. at 1. Finally, Vermont requested that "the FDA promptly establish regulations to provide for importation of prescription drugs from Canada into the [United States]" as provided by section 1121 of the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA"). Id.

In its petition, Vermont noted that the FDA is not currently

committing resources to controlling importation by individuals of prescription medications from outside the United States for their own use. Id. at 2. Vermont claimed that, because of the close proximity to Canada, "[t]he reality is that many plan members regularly travel to Canada and have the ability to bring back prescription medications under the published FDA enforcement policy." Id. Given that prescription medications are cheaper in Canada, "members are likely to import prescription medications on an ad-hoc, personal level." Id. at 3. Vermont argued that, when this occurs, VTSEMBP does not "have an opportunity to intervene to minimize the risks associated with prescription medications obtained outside the U.S., as identified by the FDA." Id.

Vermont suggested that, by granting the petition, the FDA would enable VTSEMBP to minimize any health risks associated with importing drugs. Id. As part of its program, Vermont would contract with service providers with knowledge regarding which prescription drugs sold in Canada are manufactured in FDA-approved facilities. Id. The petition suggests that "[i]f the plan was able to bring such Canadian prescription purchases back into our plan mechanism, as opposed to after-the-fact reimbursement as occurs with any other out-of-network purchase, we may be able to make those purchases subject to other safety and health promotion features of our pharmacy benefit management program, such as drug-interaction warnings and disease

management." Id.

The FDA denied Vermont's citizen petition eight months after it was filed. In its response, the FDA discussed the import provisions of the Federal Food, Drug and Cosmetic Act ("FDCA"). In the FDA's view, the FDCA creates a "closed" system which strictly limits the importation of prescription medications. FDA Decision at 1. The FDA claimed that the only kind of importation permitted under the FDCA is the re-importation of prescription drugs that were originally manufactured in the United States. Id. at 2. Even this kind of re-importation is only permitted for the original United States manufacturer of the drug. Id. The FDA stated that, given these strict legal limits on the importation of drugs, "it would be extremely unlikely that the State of Vermont could ensure that all the Canadian drugs that VTSEMBP helped its members obtain were in full compliance with all laws and regulations applicable to FDA-approved drug products." Id. at 4.

The FDA also rejected Vermont's request that the FDA promptly issue regulations as called for by section 1121 of the MMA to facilitate the wholesale importation of prescription medications from Canada. The FDA noted that, under the MMA, it can only issue such regulations "if the Secretary of Health and Human Services . . . certifies that implementing the program would (1) pose no additional risk to the public heath and safety

and (2) result in a significant reduction in the cost of drugs to the American consumer." Id. The FDA stated that "[b]oth Secretary Thompson and former Secretary Shalala have concluded (separately) in the past that such products may pose additional risks to safety and therefore should not be imported." Id. at 5. The FDA did claim, however, that it was studying the matter of drug importation in accordance with the MMA. Id. at 4. The FDA noted that the MMA directs the Secretary of Health and Human Services ("Secretary") to submit a comprehensive study to Congress on the importation of drugs.[3] Id. at 5.

The FDA also contested some of the policy arguments raised in Vermont's petition. The FDA claimed that:

> In our experience, many drugs obtained from foreign sources that purport and appear to be the same as U.S.-approved prescription drugs have been of unknown quality. In examining imported drugs sent through the mail, FDA has identified so-called "foreign versions" of FDA-approved drugs sent through the mail, improperly labeled drugs, drugs that failed to meet special storage conditions, drugs requiring close physician monitoring, and drugs containing addictive controlled substances. Such findings show the serious risks posed by the illegal importation of prescription drugs. The Agency cannot provide adequate assurance that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA or that they are safe and effective for their intended uses.

Id. at 1. Although the FDA addressed such policy arguments, when

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[3]The MMA required the Secretary to submit the study by December 8, 2004. See Pub. L. 108-173, Title XI, § 1122, Dec. 8, 2003, 117 Stat. 2469. The report was submitted approximately two weeks late, on December 20, 2004. See HHS Report (available at http://www.os.dhhs.gov/importtaskforce/Report1220.pdf).

the decision letter is considered as a whole, it is clear that the basis of the decision is the FDA's view that Vermont's proposed plan is prohibited by law.

IV. Discussion

The policy debates surrounding drug importation are contentious and complex. However, this case presents the Court with a pure question of law. The FDA claims that, under the law, it was unable to provide any of the relief Vermont requested in its citizen petition. This means that the Court must determine if Vermont's proposal was permitted under the relevant federal statutes.

A. Importation Under the FDCA and the MMA

The FDCA creates a 'closed' system in which the FDA regulates the manufacture, marketing and labeling of drugs sold in the United States. For example, drugs must be produced in accordance with good manufacturing practice ("GMP"). See 21 U.S.C. § 351(a).[4] Even if they are not pharmacologically deficient, drugs are deemed "adulterated" if they are not manufactured in accordance with GMP. See, e.g., Nutritional Health Alliance v. Food & Drug Admin., 318 F.3d 92, 100 (2d Cir. 2003). The FDCA prohibits the introduction of any adulterated drugs into interstate commerce. 21 U.S.C. § 331(a).

[4]Unless otherwise noted, all statutory citations in this opinion are to the United States Code as in effect on the date of the FDA's decision on August 4, 2004.

Approval of new drugs is governed by 21 U.S.C. § 355. For each new drug, the FDA must approve the manufacturing process, labeling and packaging. See 21 U.S.C. § 355(b)(1). Any drug, even a foreign version of an FDA approved drug, will be an unapproved drug unless it meets all United States packaging, labeling and dosage requirements. See 21 U.S.C. §§ 331(a), (d).

Under 21 U.S.C. § 381(d)(1), no prescription drug "which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug." There are only two exceptions to this rule. First, the Secretary may authorize importation for emergency use. 21 U.S.C. § 381(d)(2).[5] Second, importation may be permitted under the MMA's importation provisions. See 21 U.S.C. § 384.

The MMA contains a provision that authorizes the Secretary of HHS to "promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States." 21 U.S.C. § 384(b). The MMA also provides that the Secretary "may grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug or device or class of prescription drugs or devices, under such conditions as the Secretary determines to be appropriate." 21 U.S.C. § 384(j)(2)(A). Thus, the MMA

[5]Clearly, Vermont's program was not limited to emergency use. Thus, this exception does not authorize Vermont's program.

contemplates both commercial and individual importation. These provisions of the MMA appear to become effective only if the Secretary certifies to Congress that importation will be safe and cost-effective. The relevant subsection provides:

> Effectiveness of section
> (1) Commencement of program
> This section [21 U.S.C. § 384] shall become effective only if the Secretary certifies to the Congress that the implementation of this section will--
> (A) pose no additional risk to the public's health and safety; and
> (B) result in a significant reduction in the cost of covered products to the American consumer.

21 U.S.C. § 384(l). Secretary Leavitt and his predecessor, former Secretary Thompson, have declined to issue a certification under this subsection.

The MMA superseded the Medicine Equity and Drug Safety Act of 2000 ("MEDS Act"). Like the MMA, the MEDS Act authorized the Secretary of HHS to pass regulations allowing commercial importation of prescription drugs. 21 U.S.C. § 384(a) (2001 Supp.). The MEDS Act also contained a certification provision conditioning importation on a certification to Congress. 21 U.S.C. § 384(l) (2001 Supp.). Former Secretaries Thompson and Shalala declined to issue a certification to Congress under the MEDS Act. Thus, when Congress enacted the MMA's certification provision, it was aware that, during the previous three years, the Secretary of HHS had declined to issue a certification under a very similar provision.

B. Vermont's Proposed Plan Violates the FDCA

There is no question that Vermont's proposed program would violate the FDCA. For example, whenever Vermont assisted in the re-importation of a drug manufactured in the United States, it would violate 21 U.S.C. § 331(t). See United States v. Rx Depot, Inc., 290 F. Supp. 2d 1238, 1245 (N.D. Okla. 2003). This will be true regardless of whether VTSEMBP or the members themselves import the drugs. VTSEMBP will violate section 331(t) if it "causes" its members to import drugs in violation of 21 U.S.C. § 381(d)(1). Thus, as Vermont's proposed plan would be highly likely to include drugs manufactured in the United States, it would lead to violations of section 331(t).

Similarly, Vermont's plan is likely to violate 21 U.S.C. § 331(a). Many Canadian drugs will have packaging and labeling that is not approved by the FDA. Also, many Canadian drugs may not have been manufactured according to GMP (even if these drugs are pharmacologically identical to drugs approved by the FDA). Thus, VTSEMBP would violate 21 U.S.C. § 331(a) by causing these drugs to be introduced into interstate commerce.

C. The MMA Does Not Authorize Vermont's Plan

As Vermont's proposed plan violates the FDCA, the crucial issue is whether the MMA provides authorization for the plan. Vermont argues that its proposed program is permitted under the MMA. Vermont is incorrect. Under section 384(l), the relevant

provisions of the MMA only become effective if the Secretary certifies to Congress that importation is safe and cost-effective. As the Secretary has not made this certification, the MMA offers no support for Vermont's program.

Vermont argues that, as a matter of statutory construction, the certification provision only applies to the commercial importation provisions of section 384 and not to the personal importation provisions. Thus, according to Vermont, the Secretary should have considered the personal importation provisions when it considered Vermont's petition. Vermont relies on a highly implausible interpretation of the statute.

Statutory interpretation should begin with the plain language of the statute. See, e.g., Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc., 447 U.S. 102, 108 (1980) ("Absent a clearly expressed legislative intention to the contrary, that language must ordinarily be regarded as conclusive."). The certification provision clearly states that "this *section* shall become effective" only if the Secretary certifies. 21 U.S.C. § 384(l)(1) (emphasis added). Thus, the Court begins with a very strong presumption that Congress meant "section" when it wrote "section."

Under Vermont's interpretation, when Congress wrote "this section" it actually meant "subsections (b)-(h) but not subsections (a) and (j)." This is a convoluted and implausible

interpretation. Moreover, Vermont's position is undermined by the fact that Congress used the term "subsection" in other provisions of section 384.[6] Clearly, when Congress intended to refer only to a particular subsection, it used the appropriate language.

Vermont argues that the title of the certification provision supports its interpretation. The certification provision is titled "commencement of program." Vermont claims that only commercial importation would result in a program. The Court disagrees. "Program" does not have as limited a definition as Vermont suggests. Any "proposed project or scheme" can be considered a program. Webster's Third New International Dictionary Unabridged 1812 (1963). If implemented, the personal importation provisions of section 384(j) would lead to a program. The provision requires the Secretary to pass regulations governing personal importation from Canada and requires Canadian sellers to register with the Secretary. 21 U.S.C. § 384(j)(3). This is no less a program than commercial importation.

Vermont also argues that its interpretation is required to avoid absurd results. The certification provision requires that the Secretary certify that implementation would "result in a

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[6]For example, immediately following the certification provision is a provision referring to "the regulations under *subsection* (b) of this section." 21 U.S.C. § 384(l)(2) (emphasis added).

significant reduction in the cost of *covered products* to the American consumer." 21 U.S.C. § 384(l)(1)(B) (emphasis added). Vermont claims that the term 'covered products' only makes sense in the context of the commercial importation. This is incorrect. Products would be also be 'covered' by regulations and guidance governing personal importation.

Overall, the only sensible way to read the statute is to assume that Congress intended the certification provision to apply to the whole of section 384. As the Secretary has not made the required certification, section 384 provides no authorization for Vermont's proposed plan.

D. The MMA Does Not Violate the Nondelegation Doctrine

Vermont claims that section 384(l) improperly delegates legislative power to the Executive Branch. Vermont asks the Court to declare section 384(l) unconstitutional and sever it from the remainder of the statute. As Vermont notes, if the certification provision were severed from the statute then the MMA would authorize commercial and personal importation from Canada. However, Vermont's argument fails at its first step. The certification provision of the MMA is constitutional.

The Supreme Court has only twice struck down a statute under the nondelegation doctrine. See A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495 (1935); Panama Ref. Co. v. Ryan, 293 U.S. 388 (1935). Moreover, both of these decisions predate

the full development of the regulatory state ushered in by the New Deal. Under current law, when Congress confers decision making authority upon an agency it must "'lay down by legislative act an *intelligible principle* to which the person or body authorized to [act] is directed to conform.'" Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 472 (2001) (quoting J.W. Hampton, Jr., & Co. v. United States, 276 U.S. 394, 409 (1928)) (emphasis added). This rule is based on an "understanding that in our increasingly complex society, replete with ever changing and more technical problems, Congress simply cannot do its job absent an ability to delegate power under broad general directives." Mistretta v. United States, 488 U.S. 361, 372 (1989).

Vermont suggests that the MMA "confers unbridled discretion on the Secretary to decide whether or not" the MMA"s importation provisions will become effective. Pls.' Mem. in Opp'n at 23 (Doc. 16). If this were true, the MMA would violate the intelligible principle test. However, Vermont mischaracterizes the MMA. Under the MMA's certification provision, the Secretary must consider whether importation would pose an additional risk to the public's health and would result in a significant reduction in the cost of covered products. 21 U.S.C. § 384(l)(1). If the Secretary certifies that importation from Canada is safe and cost-effective, then the MMA's importation program becomes effective. Id. As a result, the MMA's

certification provision provides clear guidance to the Secretary of HHS by directing the Secretary to consider safety and cost-effectiveness. This is not unbridled discretion. The Supreme Court has consistently upheld delegations that provide less guidance. See, e.g., Nat. Broad. Co. v. United States, 319 U.S. 190, 225-226 (1943) (upholding delegation to Federal Communications Commission to regulate broadcast licensing "as public interest, convenience, or necessity" require). Thus, the MMA satisfies the intelligible principle test outlined in American Trucking and Mistretta.

Vermont also claims that the MMA is unconstitutional because of its conditional nature. Section 384 is unusual in that it only becomes effective if the Secretary issues a certification. According to Vermont, the certification provision gives the Secretary the authority to decide what the law is.

The MMA is not unconstitutional because of its conditional nature. The Constitution "does not require that Congress find for itself every fact upon which it desires to base legislative action." Yakus v. United States, 321 U.S. 414, 424 (1944). The Constitution only requires that "Congress has specified the basic conditions of fact upon whose existence or occurrence, ascertained from relevant data by a designated administrative agency, it directs that its statutory command shall be effective." Id. at 424-425.

In Milk Indus. Found. v. Glickman, 132 F.3d 1467, 1473 (D.C. Cir. 1998) the court upheld a law conditioning acceptance of an interstate dairy compact upon a finding by the Secretary of Agriculture that this was in the public interest. Although Glickman dealt with Congress' Article I, § 10 powers, the court specifically noted that the Compact Consent Clause should not "be understood differently from Congress' other Article I powers for the purposes of the delegation doctrine." Glickman, 132 F.3d at 1474.

Moreover, even if section 384(l)(1) were an unconstitutional delegation of authority, this would not help Vermont. This is because the provision may not be severed from the rest of section 384. It is evident that Congress would not have enacted the other provisions of section 384 standing alone. To hold otherwise would be to assume that Congress was indifferent as to whether the Secretary considered an importation program to be safe and cost-effective. The plain language of section 384(l)(1) says otherwise. Under section 384(l)(1), the rest of section 384 is to be implemented *only* upon certification by the Secretary.

In fact, it is hard to imagine a statute that gives clearer guidance on the issue of severability. Rarely will the text of a statute address this issue so directly. Here it is obvious that all of section 384 is invalid without section 384(l)(1). Thus, if the Court were to find section 384(l)(1) unconstitutional, it

would strike all of section 384. However, as is explained above, the Court holds that the MMA's certification provision is a constitutional delegation of authority.

E. The FDA Adequately Explained its Conclusion

Vermont claims that the FDA did not adequately explain its legal conclusion in its decision letter. In its decision letter, the FDA concluded that "it would be extremely unlikely that the State of Vermont could ensure that all the Canadian drugs that VTSEMBP helped its members obtain were in full compliance with all laws and regulations applicable to FDA-approved drug products." FDA Decision at 4. At the hearing on this motion to dismiss, Vermont argued that the FDA did not provide an adequate explanation for this conclusion. 04/27/05 Tr. at 36-38. Vermont asked the Court to remand this case back to the agency so that it can provide a full explanation of its conclusions. See, e.g., State of N.Y. Dept. of Soc. Servs. v. Shalala, 21 F.3d 485, 493 (2d Cir. 1994) (where the record before the agency does not support the agency action the proper action is to remand for further investigation or explanation).

The Court finds that the FDA's decision letter adequately explains its legal conclusions. Admittedly, the FDA's conclusion appears in isolation on the fourth page of the decision letter. Nevertheless, the FDA provides a full explanation for this conclusion earlier in the letter. The second page of the

decision letter contains a thorough outline of the FDCA's structure. For example, the letter explains that only the original United States manufacturer may import a prescription drug back into the United States. FDA Decision at 2. The letter also explains that Canadian drugs often do not satisfy the FDA's requirements concerning manufacturing or labeling. Id. The FDA also cited a recent federal court decision enjoining commercial importation of Canadian drugs. Id. at 2-3 (discussing Rx Depot). Overall, the FDA adequately explained why Vermont's proposal is likely to conflict with the requirements of the FDCA.

F. The Timing of the FDA's Decision

The FDA issued its decision on August 4, 2004. The timing of this decision raises two issues. First, should the FDA have delayed its decision until after the Secretary had made a decision regarding certification under section 384(l)? Second, did the Secretary behave in an arbitrary and capricious manner by failing to issue the certification as of August 4, 2004?

Vermont argues that, rather than rejecting the petition, the FDA should have provided a tentative response. Pursuant to 21 C.F.R. § 10.30(e)(2)(iii), the FDA can delay a decision because of a need for additional information. In its decision letter, the FDA noted the Secretary was preparing a comprehensive report on drug importation for Congress. The FDA stated that "[c]ompletion of this study is critical to making an informed

decision as to whether the drug importation program in MMA can be implemented safely." FDA Decision at 5.

Vermont argues that, if the FDA considered the pending report critical to any judgment regarding drug importation, then it should have waited until after the report before denying the petition. Vermont cites no case law in support of this argument. More significantly, Vermont fails to acknowledge that its petition specifically requested that the FDA "promptly" promulgate regulations. Citizen Pet. at 2. Given that the FDA was faced with this request, it was not unreasonable for the FDA to decline to issue a tentative response. The Secretary's report was not due for over four months. Moreover, the FDA did not claim that this report would constitute the Secretary's final decision about whether to issue a certification under section 384. So, even though a tentative response may have been a viable option, it was certainly not arbitrary and capricious to deny Vermont's request for "prompt" regulations. See State Farm, 463 U.S. at 43 ("[A] court is not to substitute its judgment for that of the agency" where agency's decision is reasonable.).

Another issue is whether, as of August 4, 2004, the Secretary had unreasonably delayed taking action regarding section 384(l) certification. The Defendants argue that the timing of certification has been committed to agency discretion as a matter of law and is therefore not subject to review under

the APA. See 5 U.S.C. § 701(a)(2). The Court does not have to reach this issue, however. This is because it is clear that, at the time of the FDA's decision, the Secretary had not unreasonably delayed his decision.

The MMA superseded the Medicine Equity and Drug Safety Act of 2000 ("MEDS Act"). The MEDS Act contained importation provisions almost identical to those of the MMA. See 21 U.S.C. § 384 (2003 Supp.). Under the MEDS Act these importation provisions only took effect if the Secretary demonstrated to Congress that this would be safe and cost-effective. See 21 U.S.C. § 384(l)(1) (2003 Supp.). The MEDS Acts' certification provision is identical to that of the MMA except it requires that the Secretary "demonstrate" rather than "certify" the safety and cost-effectiveness of an importation program. Id. This means that, when Congress enacted the MMA, it was aware that the Secretary of HHS had not taken action on certification for over three years. Thus, if Congress had intended for the Secretary to make a prompt decision on certification it could have been expected to provide for this in the statute. However, rather than requiring the Secretary to issue a prompt decision, Congress left the certification provision essentially unchanged.[7]

Even more significant is the MMA's requirement that the

[7]Given this legislative history, it is difficult to escape the conclusion that Congress expected that the importation provisions of the MMA would never be implemented.

Secretary prepare a detailed study regarding importation. Under the MMA, this study was not due until December 2004. It would be unreasonable to conclude that the law required the Secretary to take action under the certification provision before that date. Thus, when the FDA rejected the petition on August 4, 2004, the Secretary had not unreasonably delayed action on certification.

A court can only compel an agency to take an action that it is under a duty to perform. Norton v. S. Utah Wilderness Alliance, 542 U.S. 55, 124 S. Ct. 2373, 2379 (2004). Vermont has pointed to no authority that establishes that the Secretary has a duty to issue a decision on certification before a particular time. Moreover, as explained above, it is clear that the Secretary had not unreasonably delayed action on this matter when the FDA rejected the petition on August 4, 2004. Thus, the Court has no authority to find the Secretary's actions unreasonable and cannot order that he issue a decision on certification.

G. Limited Certification Under § 384(l)

Vermont did not request the Secretary to issue a partial certification under section 384(l) limited to its proposed program. If Vermont had made such a request, the Secretary would have been required to consider: (1) whether the MMA allows for a certification specific to a particular state or program;[8] and (2)

[8]At the hearing, the Defendants argued that the MMA does not allow a partial or limited certification. As the Court finds that Vermont did not request such a certification, it need not

if such a certification is proper, whether Vermont's proposed program is safe and cost-effective.

At the hearing on this motion, Vermont argued that its petition "implicitly" requested certification. 04/27/05 Tr. at 45. However, as Vermont conceded, the citizen petition does not explicitly request certification. In fact, the petition requests that the Commissioner of Food and Drugs "waive or revoke the current FDA interpretation of statutes and regulations that prohibits [VTSEMBP] from establishing a program for plan participants to obtain prescription medications from sources in Canada." Citizen Pet. at 1. Thus, rather than request a partial certification, Vermont asked the FDA to change its view that re-importation is prohibited until the Secretary issues a certification under section 384(l)(1). This position was confirmed by Vermont's filings in this case where it argued that its program was legal without certification. See Pls.' Mem. in Opp'n to Defs.' Mot. to Dismiss at 18-20 (Doc. 16). Accordingly, the FDA cannot be faulted for failing to address whether a certification limited to Vermont's program would be proper.[9]

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decide this issue.

[9]This conclusion is supported by the remarkable brevity of Vermont's petition. The petition is scarcely three pages of double spaced text. In that space, the petition provides only the barest sketch of VTSEMBP's proposed program and the supposed benefits of this program. Faced with such a limited petition, it is unsurprising that the FDA's response focused on the legality the proposed program under current law.

V. Conclusion

Vermont's complaint must be dismissed as it requests relief the Court has no authority to grant. Vermont's citizen petition asked the FDA to approve a program that was, and remains, illegal. Thus, the FDA did not act arbitrarily or capriciously by denying the petition. Also, as of August 4, 2004, the Secretary had not unreasonably delayed action regarding the certification provision of section 384(l)(1).

CASE CLOSED.

Dated at Burlington, Vermont this 19th day of September, 2005.

/s/ William K. Sessions III
William K. Sessions III
Chief Judge